

IN THE SPECIFICATION

(Page 17; the paragraph at line 23)

C₁

The implant consists of a cylindrical tube with a diameter of approximately three hundred micrometers and with proximal end and a distal end for implantation into an eye to serve as a conduit for aqueous humor to bypass angle structures. Where a lateral portion of the tube is removed, ~~exposes~~ the interior of the tube ~~and creates~~ is exposed creating an open side walled portion of the tube. A cross section of the open side walled portion normal to the length of the tube is in the shape of an arch ~~with an anchor location on the tube near the proximal end~~. The tube may further comprise ~~comprises~~ a series of lateral portions where the sidewall of the tube is removed. Removed lateral portions are located serially along the length of the tube and separated by whole cylindrical portions. Lateral portions are situated in a non-overlapping configuration. A ligature is tied to each of the whole cylindrical portions whereby flow through the whole cylindrical portions is prevented until the ligature is released. A second form of anchor comprises a split end of the tube wherein the end of the tube is split multiple times.

(Page 20, the paragraph at line 19)

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FIG. 6 is ~~a schematic, clasp representation of the proximal end of the implant~~ of FIG-5 an enlarged fragmentary view of the junction between the main tubular body of the implant and a lateral peeled back portion;

C2 (Page 20; the paragraph at line 21)

FIG. 7 is a ~~schematic representation showing a ligated tie-off of an~~
~~intact segment of the implant of FIG. 5~~ an enlarged fragmentary view of the distal end
of the implant of Figures 4 and 5;

(Page 21; the paragraph at line 1)

C3 FIG. 9 is a cross section of a quadricated, C-shaped strand of the FIG. 8
implant taken along lines 9-9 of figure 8;

(Page 21; the paragraph at line 3)

FIG. 10 is a cross section of a C-shaped ~~strand~~ distal nidus of the FIG. 7
implant of Figures 4 and 5 during capsule (or bleb) formation taken along lines 10-10;

(Page 21; the paragraph at line 5)

FIG. 11 is a ~~cross section of a C-shaped strand of the FIG. 8 implant after~~
~~ligature removal and inflation of the capsule or bleb~~ view similar to that of Figure 10
but showing the inflation of the bleb following removal of the ligature;

(Page 21; the paragraph at line 8)

FIG. 12 is a schematic representation of another embodiment of the invention
~~reflecting~~ employing scalloped nidus portions extending laterally from a cutaway
portion of the implant;

C3 { (Page 21; the paragraph at line 11) }

FIG. 13 is a cross section of a scalloped portion of the FIG. 12 implant taken along lines 13-13 of Figure 12 during capsule (or bleb) formation;

{ (Page 21; the paragraph at line 13) }

FIG. 14 is a ~~cross section of the C-shaped section of FIG. 5;~~ and view similar to that of Figure 13 but showing the inflation of the bleb following removal of the ligature;

{ (Page 21; the paragraph at line 16) }

FIG. 15 is a ~~cross section of the C-shaped section of FIG. 5 of the implant tube~~ taken along lines 15-15 of Figures 4 and 5;

{ (Page 21; the paragraph at line 18) }

FIG. 16 is a ~~quadrated cross section of the C-shaped section of FIG. 5~~ implant's lateral nidus projection taken along lines 16-16 of Figures 4 and 5;

(Page 22; the paragraph at line 24)

The inserted tube may be made of latex or any other suitable, flexible material.

C4 Flexible material is chosen to prevent erosion of eye tissues in contact with the implant. The proximal end 34 comprises a whole cylindrical portion 46 which is ligated, i.e., tied off with ligature 44 as shown in FIGS. 3 and 7. The ligatures comprise slip knots for ease of removal after insertion of the implant. It is to be noted that any equivalent to a slip knot which would allow simple opening of a closed off

C4

portion could be used. Ligature 44 also serves to anchor tube 32 to the sclera at the limbus where the tube enters the anterior chamber through the needle track 48. As with most surgical intervention, in the early postoperative days, there is a seton effect, where aqueous leakage occurs along the path 48 where the implant 32 enters the anterior chamber. It is during this period that the eye is at risk due to hypotony, i.e., low pressure and possible retinal detachment. Therefore, a newly installed tube is ligated initially, until a proper capsule can grow around the implant. A lesser desired alternative to ligating the tube is use of soluble plug surrounding the tube. The weakest tissue adhesion point in the implant 32 is between the fibrous cellular capsule and the latex tubing. The implant lateral portion 38 is peeled back (similar to peeling a banana) or otherwise removed along the open side 40 of the implant to form a nidus for fibrous cell growth along a C-shaped cross ~~section~~ sections, as shown in FIGS. 15 and 16. Once ligature 44 is released, pressurized aqueous will lift the capsule away from the latex tubing and form a bleb 28. FIG. 10 shows the fibrous capsule 28 prior to release of ligature 44 and FIG. 11 shows the fibrous capsule 28 now as inflated bleb 28 after release of ligature 44. The latex tube remains free-floating within the bleb to prevent constriction, collapse, or adhesions forming inside the bleb. Alternatively, the distal tube 32 may be made of dissolvable material which is eventually sloughed off. The proximal portion must remain intact and permanently in place or else the tight limbal tissues will occlude the opening through the angle structures and aqueous passage will be blocked.

⌈(Page 24; the paragraph at line 10)⌋

The tube of the present embodiment is bifurcated at distal end 36, FIG. 4.

C4 Bifurcated portions ~~42~~ 32a and lateral portions portion 38 ~~are also~~ may be C-shaped as shown in ~~FIG. 15~~ Figures 10 and 16 respectively. Bifurcated portions ~~42~~ 32a and lateral portions portion 38 serve as nidi for fibrous tissue growth 28 as shown in FIG 10. After 5-7 days the capsule has had sufficient time to form with an appropriate thickness. Elevation of the capsule from the implant by pressurized aqueous forms a bleb that filters aqueous into subconjunctival tissues. Bifurcated portions ~~42~~ 32a serve as a second anchor after a bleb is formed around these bifurcated portions. Thereafter, ligature 50 is released thereby inflating bleb 28, FIG. 11, and allowing aqueous to pass from the anterior chamber to subconjunctival tissue.

(Page 24; the paragraph at line 25)

Referring to FIG. 5, the second embodiment reflects a replication of the middle section of the first embodiment of FIG. 4 including ligature 144 tied around intact cylindrical portions portion 146 and ~~open-sided, C-shaped open-sides 140 and the associated peeled back lateral portion 138~~. An advantage of the multiple whole cylindrical section ~~46~~ 146 and the associated ligatures ~~44~~ 144, 150, 151 and 152 of the FIG. 5 embodiment of the invention is that the length of the operable implant, i.e. the inflated bleb portion may be increased as required by removing a ligature or plurality of ligatures section-by-section in series by simply removing the ligatures in a manner well-known to one skilled in the art, in this case an ophthalmologist. ~~This procedure usually means further surgery or an additional implant. Thus the~~ The present invention offers a post-surgical ability to customize the total surface area of the implant by increasing the functional surface area without the need of further surgery or an additional implant by simply removing a ligature 44 or a series of

ligatures 144, 150, 151 and/or 152 from the whole cylinder portion(s) 146 after post-surgical intraocular pressure has been determined. It can readily be seen by one skilled in the art that the tube may contain any reasonable number of peeled back portions 138 and resulting open sides 140.

(Page 25; the paragraph at line 20)

FIG. 8 shows a third embodiment of the invention similar in all respects to the first and second embodiments except the distal end 236 is quadricated, i.e. split into four sections 242 rather than two sections ~~42~~ 32a. It can readily be seen by one skilled in the art that the distal end may be split into any reasonable number of sections. The purpose of forming the split end sections 32a, ~~42~~, 242 and the peeled back lateral portions 38 is to allow a greater surface area but minimal total length of bleb. It does not matter that the nidi formed by the split ends become increasingly smaller in cross section. As the number of splits increase, the diameter of the bleb formed will be smaller in diameter and further reduced surface tension on the capsule, resulting in thinner capsule wall. The thickest part of the capsule forming around the C-shaped section 40, is only approximately three cell is thickness.